

Docket No. AB-047U2

**Amendments to and Listing of Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Claim 1 (currently amended):** A method for stimulating at least one tissue affecting specific anatomical structures of the perineum to treat patients with incontinence, urgency, frequency, and/or pelvic pain, comprising:

providing a stimulator that generates a stimulation pulse in accordance with prescribed stimulation parameters;

providing at least one of

a) a lead connected to the stimulator, which lead included at least two electrodes and

b) a catheter connected to the stimulator, which catheter includes at least one discharge portion,

whereby the stimulation pulse is delivered to at least one tissue adjacent the electrodes or catheter discharge portion;

implanting the electrodes and/or catheter discharge portion adjacent to the at least one tissue of the perineum to be stimulated to treat incontinence, urgency, frequency, and/or pelvic pain;

implanting the stimulator at a location remote from the at least one tissue to be stimulated; and

tunneling the lead or catheter subcutaneously to the stimulator location.

**Claim 2 (withdrawn):** The method of Claim 1 wherein the stimulation pulse is an electrical pulse.

**Claim 3 (withdrawn):** The method of Claim 1 wherein the stimulation pulse is a drug infusion pulse.

**Claim 4 (original):** The method of Claim 1 wherein implanting the electrodes and/or catheter discharge portion is executed with a perineal approach, which perineal approach includes guiding an insertion tool through the skin of the perineum and depositing the electrodes and/or catheter discharge portion adjacent to the at least one tissue of the perineum to be stimulated.

Appl. No. 09/931,804

Response dated June 7, 2004

Reply to Office action of January 13, 2004

Page 2 of 10

Docket No. AB-047U2

**Claim 5 (withdrawn):** The method of Claim 1 wherein implanting the electrodes and/or catheter discharge portion is executed with a vaginal approach, which vaginal approach includes guiding an insertion tool through the vaginal wall and depositing the electrodes and/or catheter discharge portion adjacent to the at least one tissue of the perineum to be stimulated.

**Claim 6 (withdrawn):** The method of Claim 1 wherein Implanting the electrodes and/or catheter discharge portion is executed with a rectal approach, which rectal approach includes guiding an insertion tool through the anal wall and depositing the electrodes and/or catheter discharge portion adjacent to the at least one tissue of the perineum to be stimulated.

**Claim 7 (withdrawn):** The method of Claim 1 wherein the electrodes and/or catheter discharge portion are positioned adjacent to at least one of the pudendal nerve and a pudendal nerve branch.

**Claim 8 (withdrawn):** The method of Claim 1 further comprising providing a programmable memory within the stimulator for receiving and retaining the stimulation parameters.

**Claim 9 (withdrawn):** The method of Claim 1 further comprising providing a power source within the stimulator for providing operating power to the stimulator.

**Claim 10 (withdrawn):** The method of Claim 1 further comprising providing at least one external appliance for transmitting the stimulation parameters to the stimulator.

**Claim 11 (withdrawn):** The method of Claim 1 wherein said at least one tissue includes the pudendal nerve, and wherein the method treats incontinence, urgency, frequency, and/or pelvic pain.

**Claim 12 (withdrawn):** The method of Claim 1 wherein said at least one tissue includes at least one of the dorsal nerve of the clitoris and the dorsal nerve of the penis, and wherein the method treats urinary urge incontinence and/or detrusor hyperreflexia.

Appl. No. 09/931,804  
Response dated June 7, 2004  
Reply to Office action of January 13, 2004

Page 3 of 10

Docket No. AB-047U2

**Claim 13 (withdrawn):** The method of Claim 1 wherein said at least one tissue is a nerve that innervates at least one of the urethra and the detrusor muscle, and wherein the method treats urinary retention.

**Claim 14 (withdrawn):** The method of Claim 1 wherein said at least one tissue is a nerve that innervates at least one of the internal urethral sphincter, the external urethral sphincter, and an intramuscular branch of a urethral sphincter, and wherein the method treats urinary stress incontinence.

**Claim 15 (withdrawn):** The method of Claim 1 wherein said at least one tissue is a nerve that innervates at least one of the clitoris and vagina, and wherein the method treats vaginismus, dyspareunia, anorgasmia, and/or other female sexual dysfunctions.

**Claim 16 (withdrawn):** The method of Claim 1 wherein said at least one tissue is a nerve that innervates at least one of the rectum and colon, and wherein the method treats constipation, fecal retention and/or colorectal hypomotility.

**Claim 17 (withdrawn):** The method of Claim 1 further comprising providing at least one sensor to sense a physical condition, and adjusting the stimulation parameters based on the sensed condition.

**Claim 18 (withdrawn):** The method of Claim 17 further comprising adjusting the stimulation parameters using at least one external appliance.

**Claim 19 (withdrawn):** The method of Claim 17 further comprising adjusting the stimulation parameters using the implantable stimulator.

**Claim 20 (canceled)**

Appl. No. 09/931,804  
Response dated June 7, 2004  
Reply to Office action of January 13, 2004

Pag 4 of 10

Docket No. AB-047U2

**Claim 21 (withdrawn):** The system of Claim 20 wherein the stimulator is configured to generate an electrical stimulation pulse.

**Claim 22 (withdrawn):** The system of Claim 20 wherein the stimulation is configured to generate a drug infusion stimulation pulse.

**Claim 23 (withdrawn):** The system of Claim 20 further comprising means for implanting the electrodes and/or catheter discharge portion adjacent to at least one of the pudendal nerve and a pudendal nerve branch.

**Claim 24 (withdrawn):** The system of Claim 20 wherein the stimulator includes a programmable memory for receiving and retaining the stimulation parameters.

**Claim 25 (withdrawn):** The system of Claim 20 further comprising a power source for providing operating power to the stimulator.

**Claim 26 (withdrawn):** The system of Claim 25 wherein the power source is housed within the stimulator.

**Claim 27 (withdrawn):** The system of Claim 26 wherein the power source is rechargeable.

**Claim 28 (withdrawn):** The system of Claim 20 further comprising at least one external appliance for transmitting power to the stimulator.

**Claim 29 (withdrawn):** The system of Claim 20 further comprising at least one external appliance for transmitting the stimulation parameters to the stimulator.

**Claim 30 (withdrawn):** The system of Claim 20 further comprising at least one sensor, and wherein the stimulation parameters are adjusted based on the sensed condition.

Appl. No. 09/931,804  
Response dated June 7, 2004  
Reply to Office action of January 13, 2004

Page 5 of 10

Docket No. AB-047U2

**Claim 31 (original):** A method of treating patients with incontinence, urgency, frequency, and/or pelvic pain, comprising:

providing a stimulator that generates a stimulation pulse in accordance with prescribed stimulation parameters;

providing at least one of

a) a lead connected to the stimulator, which lead includes at least two electrodes and

b) a catheter connected to the stimulator, which catheter includes a discharge portion

whereby the stimulation pulse is delivered to at least one tissue adjacent the electrodes or catheter discharge portion;

perineally or vaginally implanting the electrodes and/or catheter discharge portion adjacent to at least one tissue to be stimulated;

implanting the stimulator at a location remote from the at least one tissue to be stimulated; and

tunneling the lead and/or catheter subcutaneously to the stimulator location.

**Claim 32 (original):** The method of Claim 31 wherein the at least one tissue to be stimulated includes at least one of a periurethral muscle, urethral sphincter, anal sphincter, pudendal nerve, clitoral branch of the pudendal nerve, penile branch of the pudendal nerve, inferior rectal branch of the pudendal nerve, urethral branch of the pudendal nerve, pelvic nerve, and pelvic floor nerves.

**Claim 33 (original):** The method of Claim 32 wherein the stimulation is delivered at less than about 50 to 100 Hz.

**Claim 34 (original):** The method of Claim 31 wherein the at least one tissue comprises at least one of the somatic nerves that originate from the sacral nerve roots.

Appl. No. 09/931,804

Response dated June 7, 2004

Reply to Office action of January 13, 2004

Page 6 of 10

Docket No. AB-047U2

**Claim 35 (original):** The method of Claim 34 wherein the at least one tissue comprises at least one of the pudendal nerve and a pudendal nerve branch.

**Claim 36 (original):** The method of Claim 31 wherein the at least one implantable stimulator further comprises at least one sensor.

**Claim 37 (original):** The method of Claim 36 further comprising sensing a condition using the at least one sensor and adjusting the stimulation parameters based on the sensed condition.

**Claim 38 (original):** The method of Claim 37 further comprising performing the parameter adjustment using at least one external appliance.

**Claim 39 (withdrawn):** The method of Claim 37 further comprising performing the parameter adjustment using the implantable stimulator.

Appl. No. 09/931,804  
Response dated June 7, 2004  
Reply to Office action of January 13, 2004

Page 7 of 10